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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,711	04/13/2006	Hiroyuki Ebinuma	289613US0X PCT	3268
22850	7590	12/12/2008	EXAMINER	
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314				DUFFY, PATRICIA ANN
ART UNIT		PAPER NUMBER		
		1645		
NOTIFICATION DATE			DELIVERY MODE	
12/12/2008			ELECTRONIC	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com  
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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/575,711	EBINUMA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 05 September 2008.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 5-9 and 13 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-4 and 9-12 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 13 April 2006 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/06; 7/06; 3/07</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|   | 6) <input type="checkbox"/> Other: _____.                         |

#### **DETAILED ACTION**

The response filed 9-5-08 has been entered into the record.

##### *Priority*

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

##### *Drawings*

The drawings in this application have been accepted. No further action by Applicant is required.

##### *Information Disclosure Statement*

The information disclosure statements filed 4-06, 7-06 and 3-07 have been considered. Initialed copies are enclosed.

##### *Election/Restrictions*

Applicant's election with traverse of Group I, claims 1-4 and 9-12 in the response filed 9-5-08 is acknowledged. The traversal is on the ground(s) that the search of all the claims of Groups I-III is not a search burden and all the claims should be examined pursuant to MPEP section 803. This is not found persuasive because search burden is not a criteria with respect to Lack of Unity. Lack of Unity in an application filed under 35 USC 371 is governed by PCT Rule 13.1 and 13.2. The claims lack unity of invention, search burden is irrelevant to the determination of a Lack of Unity. Applicants request that if Group I be found allowable that the Office should expand its search to Groups II and III. The search will not be expanded to the non-elected products because where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the

limitations of the allowable product claim will be considered for rejoinder. In the instant case Applicants have not elected the product and as such, the product claims will not be rejoined in any event.

The requirement is still deemed proper and is therefore made FINAL.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 and 9-12 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the method steps of performing an immunological assay vise a vie contacting the sample with an antibody and detecting binding of antibody.

*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, and 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Waki et al (The Journal of Biological Chemistry, 278(41):40352-40636, 10 October 2003; of record on 1449).

Waki et al teach an immunoblot assay wherein a sample containing adiponectin is contacted with a SDA-PAGE 5X sample buffer containing 3% SDS, 50 mM Tris-HCl pH 6.8, 5% 2-mercaptoethanol and 10% glycerol and optionally 10 mM dithiothreitol for complete reduction serum samples (i.e. the instant "at least one of" a reducing agent, an acid or salt thereof and a surfactant). The sample was mixed with 5X sample buffer and incubated

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for 1 hour at room temperature. For immunooblotting proteins separated by SDA-PAGE were transferred to nitrocellulose membranes, The membranes were blocked with TBS-T and then incubated with diluted antiserum for one hour at room temperature (i.e. the instant "use of an insoluble carrier on which an anit-adiponectin antibody is put"). After washing the membranes were incubated with horesradish peroxidase-conjugated anti-rabbit antibody and the binding was detected using ECL western blotting detection. (see page 40353, column 2, third and fourth full paragraph and page 40355, column 1, Figures 2A and 2B and legend).

As such, the art is deemed to anticipate the claims since the reagent is not seen to require the presence of the protease. In otherwords, the presence of the protease is optional in that not all of the reagents are required in a treatment buffer.

Claims 1-4, and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freubis et al (PNAS 98(4):2005-2010, Feb 13, 2001; of record).

Freubis et al teach immunoassay blotting of Acrp30 (adiponectin) treated with acetylated trypsin that contains the entire globular head region and migrates with an apparent molecular was of 16kDa (Fig 1C, Lane IV). Freubis et al teach that the fragment is more potent than full length protein and that it is presumed that Acrp30 undergoes proteolysis to generate the C-terminal fragment. Immunoprecipitation studies indicate that plasma has a small mount of the human homolog, apm-1, containing the globular domain of the protein. The source of the trypsin does not structurally distinguish it from that of the prior art (claims 2 and 3). Freubis et al differ by not measuring the amount of gAcrp30 by immunoassay.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time that the invention was made to treat serum/plasma with acetylated trypsin in order to detect the total adiponectin (gAcrp30 + Acrp30) by immunoassay according to Freubis et al because Freubis et al teach that the fragment is more potent than full length protein

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and that it is presumed that Acrp30 undergoes proteolysis to generate the C-terminal fragment and that the fragment is the active fragment. Pre-treatment conversion of the Acrp30 to gAcrp30 would provide the advantage of having a single homogenous low molecular weight protein to assay.

*Status of the Claims*

Claims 1-4 and 9-12 stand rejected. Claims 5-8 and 13 are withdrawn from consideration.

*Conclusion*

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-Th 6:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor Robert Mondesi can be reached at 571-272-0956.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Patricia A. Duffy/

Primary Examiner